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10/055,746	01/23/2002	Robert Miller	60159P1	7363

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 05/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,746

Applicant(s)

MILLER, ROBERT

Examiner

Medina A Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 1-47 are pending and are under examination.

Claim Objections

Claims 1-2, 20, and 46 (and dependents 3-19, 21-45 and 47) are objected to for failing to recite complete ATCC accession information. The claims should be amended to recite the accession information as appropriate.

Claims 5 and 18 are objected to because "a plant according to claim 2" and "a maize plant according to claim 2", respectively, lack a proper article. It is suggested that "a" in line 2 of claim 5 and line 1 of claim 18, is replaced with ---the-----.

Claims 6 and 8 and dependents 7, 9-17 fail to further limit parent claims.

Claim 8 lacks proper article. "A" should be changed to --The--.

In claim 18, depending upon claim 2, "plants " in line 3, should be changed to ---the maize plant---.

Claims 19, 26-28, and 36-38 "A" should be changed to ---The---, for proper article.

Claim 19 fails to further limit in its recitation "or being protoplasts or callus derived therefrom"

In claim 47, "said a single gene trait" should be changed to ---said single gene trait---, for clarification.

Claims 36 and 26 don't further limit parent claims 35 and 25, respectively, because of "or" in line 3 of the parent claims.

Objection to the specification

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The specification is objected to for reciting incomplete ATCC accession information in page 21, line 14. The specification is also objected to for the inclusion of a hyperlink directed to an Internet address, on page 14, line 9, and on page 17, line 28, for example. The use of hyperlinks is not permitted under USPTO current policy because the content of such links are subject to a change, resulting in the introduction of New Matter into the specification. Appropriate correction is required.

Claim Rejections - 35 USC § 112, 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 1-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite in the recitation "NP2276". Since the name "NP2276" is not known in the art, the use of said name does not carry art-recognized limitations as to the specific or essential characteristics that are associated with that denomination. The name "NP2276" does not clearly identify the claimed seeds, plants, and plant parts, and does not set forth the metes and bounds of the claimed invention. The name appears to have been arbitrarily assigned and can be changed. The specific characteristics associated therewith can also be modified. Amending claims 1-2, 20 and 46 to recite the ATCC deposit number in which seed of maize inbred line NP2276 has been deposited would overcome the rejection.

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In claim 10, "the line PH2EJ" lacks antecedent basis.

Claims 11 and 13 are indefinite because "one or more transgenes comprising a gene " does not make sense. Dependent claims 12 and 14-16 are included in the rejection.

Claim 16, depending from claim 6, is confusing in the recitation of "wherein said Cry1Ab gene is introgressed into said maize plant..." because it is unclear if the introgressed gene is in addition to the one or more transgenes of claim 6.

Claims 18 and 20 are indefinite in the recitation of "capable of expressing" which implies the plant may or may not have all of the physiological and morphological characteristics of NP2276 plant. It is suggested that phrase be replaced with ---having--.

Claims 21, 31 and 45 are indefinite in the recitation of "good", "acceptable to good", "above average", adapted to", "excellent", early", and "reliable" which are relative terms lacking comparative basis. The specification fails to clarify the use of these terms.

Claims 22, 32 and 46 are indefinite for lacking defined method steps. The claims are also indefinite in the recitation of "using" (claims 22, 32 and 46) and "employing" (claim 22 and 32) without any positive method steps by which one could practice the claimed method.

Claim 23 is indefinite in the recitation of "The maize plant breeding program of claim 22", because claim 22 is drawn to a method for developing a maize plant rather than a breeding program.

Claim 33 is indefinite in the recitation of "The maize plant breeding program of claim 32, because claim 32 is drawn to a method for developing a maize plant rather than a breeding program.

Claim 41 is indefinite because it is unclear what the method is for. The preamble is incomplete. In addition, no steps for identifying (part c) and no steps for selecting (part d) the plants are also recited a plant. Dependent claims 44-45 are included in the rejection.

Claim 42 is indefinite for lacking correlation between the preamble and last method step. The preamble recites a method for producing maize plant, and the resultant product is progeny maize seed. Also, step c indicates that one obtains seed by growing a seed.

Claims 43 is indefinite in the recitation of "said maize plant of method 42". If Applicant intends ---the maize plant of claim 42---, then, it is unclear if maize plant is produced by the method of claim 42 (progeny maize seed is produced rather than a maize plant). The claim is also indefinite in the recitation of additional "NP2276-derived" plants or seeds because no NP2276-derived plant is recited in claim 42. Also, would "derived" mean "isolated" or "progeny" or something else? What is encompassed in the derived plant/seed is unclear. Dependent claims 44-45 are included in the rejection.

In claim 46, a "single gene trait" is unclear, as the term does not carry with it any limitation as to the structural or physiological properties of the gene. The sentence on page 17, lines 1-2, recites, "the genes responsible for a single gene trait...(emphasis added) which indicates that more than one gene confers the single gene trait. The

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specification does not clearly define a "single gene trait", and therefore, the term is open to a variety of interpretations.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Since the seed claimed is essential to the claimed invention, it must be obtainable by a reproducible method set forth in the specification or otherwise be readily available to the public. The specification does not disclose a reproducible method to obtain the exact same seed and it is unclear if the seed is readily available to the public.

The statement on page 21 of the specification indicating that Applicants have made a deposit of the claimed inbred maize line NP2276 with the ATCC is noted. However, there is no indication that the seed has been deposited and no indication that the seed is available to the public. A deposit of at least 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or statement by an attorney of record over his or her signature and registration number, stating that the seed has been deposited under the Budapest Treaty and the seed will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. See 37 C.F.R. 1.808-1.809 for additional explanation of these requirements.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, Applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 days or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see C.F.R. 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Enablement

Claims 16, 41 and 46-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for introgressing a single gene trait into a maize plant of inbred line NP2276 via breeding methods.

Applicant has not disclosed or provided guidance for the introgression of a single gene by backcross breeding, wherein said introgression should result in successful expression of the desired trait but should not interfere with expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked or unlinked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, Applicant has not provided guidance for introgression of any and all single genes from a multitude of non-disclosed and uncharacterized parentals into the claimed variety,

Hunsperger et al (US Patent No. 5, 523, 520) disclose that a specific gene trait in the genetic background of one plant which has been introgressed into the genetic background of another plant of the same species didn't result in the expected transfer of the single gene trait (column 3, lines 26-46). Kraft et al (Theor. Appl. Genet. 2000, vol. 101, pp. 323-326) teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single transferred trait, and that such effects are

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unpredictably genotype specific and loci dependent in nature. Kraft et al teach that linkage disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is known about the plant breeding material, and therefore, there is an unpredictable effect in plant breeding (page 323, column 1, line 7 to line 15). Finally, Eshed et al (Genetics, vol. 143, pp1807-1817, 1996) teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (page 1815, column 1, line 1 to page 1816, column 1, line 1). Neither the instant specification nor the prior art provides guidance for obviating the problems of obviating linkage disequilibrium linkage drag, or epistatic effect in maize breeding materials, such that a single gene trait can be successfully transferred from one genetic background to another.

Claim 41 is included in the rejection because Applicant has not disclosed or provided guidance for how to identify the claimed inbred plants from a collection of other plants or disclosed a repeatable process to reproduce the claimed seed. Therefore, one skilled in the art would not be able to practice the claimed method without undue experimentations.

Therefore, given the lack of guidance in Applicants' specification regarding transfer of a single gene trait by backcrossing into Applicant's maize line while retaining all of the other genotypic and phenotypic characteristics, the state of the art, the unpredictability inherent in single gene transfer, and lack of working examples, one

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skilled in the art would not be able to make and/or use the invention, without undue experimentations.

Written Description

Claims 6-10, 17, 21-24, 29-34, and 39-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention lacks written description under the current written description guidelines. The claims are drawn to maize plants of an undisclosed number of generations that are only known to have at least one ancestor of NP2276 maize plant, NP2276-derived plants/seed obtained by repeated crossing of a NP2276 maize plant or with another non-NP2276 maize plant by a number of generations. These are genus claims. Applicant only describes inbred maize line NP2276 having specific combination of genotypic and phenotypic characteristics. Applicant has not described the morphological and/or genotypic characteristics for all hybrid maize plants and seeds of claims 29-30 and 39-40 produced by crossing the inbred maize line NP2276 with another unidentified maize plant. No specific morphological or genotypic characteristics that distinguish F1 hybrid maize plants/seeds from other maize plants and seeds are described. Since Applicant has not described even F1 generation plants and seed, methods for using F1 hybrid plant/seed or inbred plant NP2276 as a source of breeding material or as an ancestor as claimed in claims 22-23, 32-33 and 42-43 to produce

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subsequent generation plants of claims 21, 24, 31, 34 and 44-45 are similarly not described. Furthermore, since Applicant has not described the breeding partners involved in crossing with the exemplified plant, or the resultant product, Applicant also has not described methods for using the products in subsequent generations of outcrossing to uncharacterized breeding partners, or the resultant products of said multiple outcrosses. See claims 21, 31 and 45. The only characteristics recited in the claims for the plants of claims 21, 31, and 45 are the expression of the combination of at least two traits which were described with relative terms that lack comparative basis (see rejection under 112, 2nd paragraph).

The Federal Circuit court stated that a written description of an invention "requires a precise definition, such as by structure, formula [or] chemical name, of the claimed subject matter sufficient to distinguish it from other material". *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997). The court also stated "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of is not a description of that material". *Id.* Further, the court stated that to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of members of the genus". *Id.* In the instant application, the disclosure of a single maize inbred line, NP2276, does not provide adequate written description for the claimed genus, F1 or subsequent generation plants or a method for using them to produce NP2276-derived or further derived plants, wherein only one ancestor of the plant is known to be NP2276, and the

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rest of the ancestors are unknown. In addition, because various breeding techniques (claims 22-23, 32-33) and a number of uncharacterized breeding partners and breeding generations have been employed, substantial variation in structure and phenotypes are expected among the resultant plants.

Claims 6-10 and 46 are included in the rejection because Applicant has not described a multitude of non-exemplified transgenes and single gene traits or their phenotypic effects in particular maize genetic background. In addition, the claims do not characterize the sequence or identity of the transgenes and single gene traits or recite phenotypic effects. The phenotypic and/or genotypic characteristics of a plant comprising one or more genes of unknown phenotypic effects are not described. Accordingly, the claimed invention lacks adequate written description as required under the current written description guidelines (See Written Description Requirement published in Federal Registry/Vol.66, No. 4/Friday, January 5, 2001/Notices; P. 1099-1111).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claim 42 is rejected under 35 U.S.C. 102(b) as being anticipated by Kramer (US 5, 929, 313).

The claim is drawn to a method for producing a progeny maize plant by crossing a first parent plant with a second parent plant, harvesting and growing the first generation seed to yield a progeny maize plant.

Kramer teaches a method for producing hybrid maize plants by crossing the inbred maize line PHMJ2 with another maize plant, harvesting F1 seeds and growing said F1 seed to produce hybrid plants (see at least the abstract). Kramer teaches all claim limitations.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21-24, 29-34, 39-40, and 42-45 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Puskaric (US 5, 977, 456)

Claims are drawn to inbred maize line designated as "NP2276", plants/ seeds thereof and progeny plant/seed including F1 hybrid produced by crossing the inbred maize line NP2276 with unidentified maize lines and a method of using F1 hybrid plants to produce subsequent generation plants, NP2276-derived plants, and various breeding methods used.

Puskaric teaches plants and seed of an inbred maize line designated "PH1M7," and methods for producing hybrid seeds and plants including F1 and subsequent generation plants, wherein a plant of inbred line PH1M7 is crossed with another inbred corn plant, F1 hybrid and subsequent generation maize seed and plants. The reference further teaches maize breeding programs, including backcrossing, pedigree breeding, and recurrent selection (columns 1-3, 15-16 and 20-22; claims). It appears that the claimed plants and seeds of the instant invention may be the same as PH1M7, given that they exhibit similar traits associated with plant morphology such as leaves with medium green color, red cob, and agronomic characteristics such as high yield, good seedling vigor and resistance to insect and other diseases resistance (col. 10, lines 47-59).

Hence, the instantly claimed progeny plants are indistinguishable based on the teachings of the specification from the prior art PH1M7 corn line.

Alternatively, if the claimed progeny plants, plant parts, and seeds produced from NP2276 are not identical to PH1M7, then it appears that they differ from the PH1M7 plants, plant parts, and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur upon cultivation of said plants on

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different soil types with different nutrient supplements and under different environmental growth conditions such as temperature, humidity, light, etc. in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to PH1M7.

Since Applicant has not disclosed specific morphological and/or physiological characteristics for the claimed F1 generation plants /seeds, the claimed plants are deemed to be anticipated by or obvious over the PH1M7 plants/seeds of the prior art, especially since the second parent plants involved in the crossing are unknown. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejected over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Therefore, the claimed invention is anticipated by or, in the alternative, is obvious over the prior art, absent evidence to the contrary.

Remarks

Claims 1-20, 25-28, 35-38, 41 and 45-47 are deemed free of the prior art of record. The closest prior art corn line is the PH1M7 corn line of Puskaric. However, the instantly claimed NP2276 corn line differs from the prior art corn line in that it has plant height of 203 cm, ear length and height of 13.9 cm and 64 cm, respectively, tassel with 3 primary branches, cob diameter of 21 mm, and 14 kernel rows, and resistance insects and to Stewart' wilt diseases.

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Remarks

No claim is allowed.

Papers related to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmission 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday-Thursday from 8:30AM to 5:30PM and every other Friday 9:00AM to 5:00PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

5/14/03

Mai



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